

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Highlights:

- The Department of Health and Human Services (HHS) works to enhance the health and well-being of Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.
- The Budget supports critical investments to enable HHS to deliver on its mission, while also reducing
  funding or eliminating programs that are ineffective, inefficient, or duplicative. The Budget saves taxpayer
  dollars and helps move toward the President's vision of an accountable Government that is effective and
  efficient in its delivery of programs.
- The Budget addresses some of the Nation's most pressing public health needs, investing in efforts to combat the devastating opioid epidemic, making new investments in programs to treat individuals suffering from severe mental illness, and accelerating work on ending infectious diseases. The Budget invests in biomedical research, increases accountability for research dollars, and enhances the Government's preparedness for responding to infectious disease outbreaks or other man-made disasters. The Budget also includes proposals to lower drug costs, strengthen and protect the Medicare program, repeal and replace Obamacare, and provide States more flexibility in Medicaid.
- The Budget continues to invest in key programs and proposes innovative solutions that promote child well-being, build stronger families, and help low-income Americans move from welfare to work.
- The Budget requests \$68.4 billion for HHS, a \$17.9 billion or 21-percent decrease from the 2017 enacted level. This Budget funding level includes additional funds for program integrity and implementing the 21st Century CURES Act and the 2017 enacted funding levels do not include actual fee collections and contract support costs. The Budget proposes \$295 billion in mandatory savings, helping to put Federal spending on a sustainable path. In addition, the Budget includes \$675 billion in net mandatory savings across HHS and the Department of the Treasury to repeal and replace Obamacare.

#### The President's 2019 Budget:

The Budget shows a clear commitment to a better future for all Americans and funds the highest priority HHS activities, such as addressing the opioid crisis, serious mental illness, and emergency preparedness. The Budget strengthens Medicare, repeals and replaces Obamacare, comprehensively reforms Medicaid, and includes a strong focus on program integrity for all health programs.

The Budget delivers on the President's vision to reorganize the Government to improve efficiency, effectiveness, and accountability by putting forward proposals to reorganize HHS. These include: improving the management of the Strategic National Stockpile; streamlining the administrative functions at the National Institutes of Health (NIH); and improving efficiency through examining the effectiveness of the U.S. Public Health Service Commissioned Corps. The Budget also integrates the research of three programs—the Agency for Healthcare Research and Quality, the National Institute for Occupational Safety and Health, and the National Institute on Disability, Independent Living, and Rehabilitation—within NIH to improve coordination and outcomes. Initially, these activities would be established as separate Institutes, but NIH will assess the feasibility of integrating these research activities more fully into existing NIH Institutes and Centers over time.

Combats the Opioid Epidemic. The Budget significantly strengthens efforts to combat the opioid epidemic by including \$5 billion in new resources over the next five years. Approximately 64,000 people died in 2016 as the result of drug overdoses, the largest increase in drug deaths ever recorded in a single year in the United States. Deaths from drug overdoses have almost doubled in the last 10 years, and drug overdose is the leading cause of unintentional injury deaths for Americans under the age of 50. A major driver of this crisis is opioids, a class of drugs that includes both legal and illicit drugs such as certain prescription painkillers, heroin, and synthetic opioids such as fentanyl.

The Budget builds upon the Administration's continued efforts—in 2017, the Administration declared a nationwide public health emergency and provided nearly \$500 million to States to prevent and treat opioid abuse and addiction; in addition, the 2018 Budget requested another \$500 million. The Budget requests \$1 billion in new resources for 2019 and a total of \$5 billion over the next five years to combat the opioid epidemic by preventing abuse and helping those who are addicted get access to overdose reversal drugs, treatment, and recovery support services.

The Administration will increase awareness of the dangers of opioids through a national media campaign,

encourage safer prescribing practices to reduce unnecessary prescriptions, and help States improve their Prescription Drug Monitoring Programs. The Administration will continue its work to develop innovative technologies to replace the use of opioids in pain management and to prevent addiction to opioids. In addition, the Administration supports more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

For Medicaid, the Budget proposes expanding coverage of comprehensive and evidence-based Medication Assisted Treatment options, previews forthcoming guidance from the Centers for Medicare & Medicaid Services (CMS) that would set minimum standards for State Drug Utilization Reviews to reduce clinical abuse, and requires States to track and act on high prescribers and utilizers of prescription drugs.

# Where to find help for addiction to opioids and other substances

The Substance Abuse and Mental Health Service Administration's National Helpline, 1-800-662-HELP (4357) provides a free, 24-hour-a-day, 365-day-a-year, information (in English and Spanish) for individuals and family members facing mental illness and/or substance abuse issues. This confidential service provides referrals to local treatment facilities, support groups, and communitybased organizations. Callers can also order free publications and other information. Callers are not asked for any personal information other than their zip code or other geographic information in order to accurately identify the local resources appropriate to the caller's needs. Referral information can also be searched online at https://findtreatment.samhsa.gov/.

For Medicare, the Budget proposes to test and expand nationwide a bundled payment for community-based medication assisted treatment, including, for the first time, comprehensive Medicare reimbursement for methadone treatment. The Budget also proposes to prevent prescription drug abuse in Medicare Part D and protect beneficiaries from potentially harmful drugs by requiring plan participation in a program to prevent prescription drug abuse, which would promote sound public health policy and help keep premiums down for seniors.

In addition, the Budget proposes to authorize the Secretary to work with the Drug Enforcement Administration to revoke a provider's certificate (which allows a provider to prescribe controlled substances) when that provider is barred from billing Medicare based on a pattern of abusive prescribing.

Reforms Drug Pricing and Payment. The goal of the Administration's comprehensive strategy is to address the problem of high drug prices, provide greater access to lifesaving medical products, and ensure that the United States remains the leader in biomedical innovation. The Budget proposes new strategies to address high drug prices, increase access to lifesaving medicines, rationalize the current payment incentive structure in Medicare Part D and Part B, and foster greater competition among generic pharmaceutical firms.

- Tests Innovative Medicaid Drug Coverage and Financing Reforms—the Budget calls for new Medicaid demonstration authority for up to five States to test drug coverage and financing reforms that build on private sector best practices. Participating States would determine their own drug formularies, coupled with an appeals process to protect beneficiary access to noncovered drugs based on medical need, and negotiate drug prices directly with manufacturers. HHS and participating States would rigorously evaluate these demonstrations, which would provide States with new tools to control drug costs and tailor drug coverage decisions to State needs.
- Speeds Development of More Affordable Generics—the Budget proposes to give the Food and Drug Administration (FDA) greater ability to bring generics to market faster by incentivizing more competition among generic manufacturers. This would lead to greater access for consumers to safe, high-quality, and affordable generic drugs and would improve health and quality of life through FDA's advances in shaping medical practices. The proposal ensures that first-to-file generic applicants who have been awarded a 180-day exclusivity period do not unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period. Under this proposal, when a first-to-file generic application is not yet approved due to deficiencies, FDA would be able to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock, rather than waiting an indefinite period for the first-to-file applicant to fix the deficiencies in its application. Triggering the start of the 180 day-exclusivity period for first-to-file applicants who "park" their exclusivity would speed delivery of generic drugs and provide substantial cost savings to American consumers.
- Modernizes the Medicare Part D Drug Benefit and Modifies the Part B Drug Payment—the Budget addresses the misaligned incentives of the Part D drug benefit structure and better equips plans with the tools necessary to manage spending. Proposed changes are designed to: lower beneficiary costs at the pharmacy counter by requiring plans to share at the point of sale a portion of rebates that plans receive from drug manufacturers; enhance Part D plans' negotiation power with manufacturers by allowing for additional flexibilities in formulary management; encourage utilization of higher value drugs by eliminating cost-sharing for generic drugs for beneficiaries who receive the low-income subsidy; modify the Part D payment structure to discourage drug manufacturers' price and rebate strategies that increase spending for both beneficiaries and the Government; and provide beneficiaries with more predictable

annual drug expenses through the creation of a new out-of-pocket spending cap. In addition, the Budget modifies payment for Part B drugs to discourage manufacturers from increasing prices faster than inflation and improve payment accuracy. The Budget also modifies hospitals' payment for drugs acquired through the 340B drug discount program by rewarding hospitals that provide charity care and reducing payments to hospitals that provide little to no charity care.

Repeals & Replaces Obamacare and Reforms Medicaid Financing. Obamacare, which substantially shifted regulatory power from the States to the Federal Government in order to standardize coverage, has wreaked havoc on the individual insurance market. Average premiums increased 105 percent from 2013 to 2017 while choices have dwindled. In 2017, people in one-third of U.S. counties only had a single insurer from which to purchase a plan on an exchange. For 2018, approximately 30 percent of enrollees only had choices from a single insurer.

"We will deliver relief to American workers, families, and small businesses, who right now are being crushed by Obamacare, by increasing freedom, choice, and opportunity for the American people."

President Donald J. Trump March 10, 2017 While many people with expensive medical conditions and those with income sufficiently low enough—below 200 percent of the Federal poverty level—to receive large subsidies have obtained coverage, the exchanges have failed to attract healthier individuals and families with somewhat higher incomes that want affordable options that meet their needs. In addition, the Patient Protection and Affordable Care Act's (PPACA) Medicaid expansion has cost significantly more than expected. For example, in 2015, CMS actuaries increased their estimates of Federal spending for the average Medicaid expansion enrollee in that year by almost 50 percent. Overall, the cost per newly insured individual is far more than what was expected.

The Budget supports a two-part approach to repealing and replacing Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson (GCHJ) bill as soon as possible, followed by enactment of additional reforms to help set Government healthcare spending on a sustainable fiscal path that leads to higher value spending. The President is committed to rescuing States, consumers, and taxpayers from the failures of Obamacare, and supporting States as they transition to more sustainable healthcare programs that provide appropriate choices for their citizens. The Budget also provides a path for States and consumers to be relieved from many of the PPACA's insurance rules and pricing restrictions that have resulted in one-size-fits-all plans with soaring premiums and deductibles. This would allow people to buy insurance plans that work for them and that are fairly priced, a substantial benefit to middle class families who do not receive coverage through the workplace.

The Market-Based Health Care Grant Program would provide more equitable and sustainable funding to States to develop affordable healthcare options. The block grant program would promote structural reforms to improve the functioning of the healthcare market through greater choice and competition, with States and consumers in charge rather than the Washington bureaucracy. The Budget would allow States to use the block grant for a variety of approaches in order to help their citizens, including those with high cost medical needs, afford quality healthcare services. The block grant approach also reflects the Administration's view that Government subsidies are better targeted to States and consumers rather than funneled through insurance companies as with the PPACA.

The President is also committed to the comprehensive Medicaid reform in the GCHJ bill, including the repeal of the Obamacare Medicaid expansion and reducing State gimmicks, such as provider taxes, that raise Federal costs. Medicaid financing reform would empower States to design individual, State-based solutions that prioritize Medicaid dollars for the most vulnerable and support innovations such as community engagement initiatives for able-bodied adults. National healthcare spending trends are unsustainable in the long term and the Budget includes additional proposals to build upon the GCHJ bill to make the system more efficient, including proposals to align the Market-Based Health Care Grant Program, Medicaid per capita cap, and block grant growth rates with the Consumer Price Index (CPI-U) and to allow States to share in program savings.

This two-part approach in the Budget ensures that States have the financial support they need to transition away from Obamacare, while allowing greater choice and competition in healthcare markets and more sustainable Government health spending over the long term.

Provides States with Flexibility to Modernize Medicaid. In addition to the program flexibilities included in the Budget proposal to repeal and replace Obamacare, and building on the recent Administration guidance allowing States to explore community engagement requirements for ablebodied adults in Medicaid, the Budget proposes to empower States to further modernize Medicaid benefits and eligibility. The Budget would give States additional flexibility around benefits and cost-sharing, allow States to consider savings and other assets when determining Medicaid eligibility, and reduce waste by counting lottery winnings as income for Medicaid eligibility. These proposals enable the Federal and State governments to be partners in greater fiscal responsibility which would preserve and protect the Medicaid program for Americans who truly need it.

Improves Program Integrity for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Budget includes legislative proposals and administrative actions to strengthen the integrity and sustainability of Medicare, Medicaid, and CHIP. Combined with additional funding investments, these policies would provide CMS with additional resources and tools to combat fraud, waste, and abuse and to promote high-quality and efficient healthcare.

To improve fiscal integrity and transparency in Medicaid payment policy, CMS will propose guidance to improve timely and complete data collection on Medicaid supplemental payments, including the financing of such payments. In addition, current law allows States to make Medicaid provider payments far in excess of actual service costs. States have used this additional money to leverage Federal reimbursements in excess of their Medicaid matching rate or for other purposes. To avoid

# Health Care Fraud and Abuse Control: \$5 returned for every \$1 spent

Additional funding for the Health Care Fraud and Abuse Control (HCFAC) program has allowed CMS in recent years to shift away from a "pay-and-chase" model toward identifying and preventing fraudulent or improper payments from being paid in the first place. The return on investment for the HCFAC account was \$5 returned for every \$1 expended from 2014-2016. The Budget proposes HCFAC discretionary funding of \$770 million in 2019, which is \$45 million higher than the 2017 enacted level.

this misuse of funds, the Budget also proposes to limit reimbursement to Government providers to no more than the cost of providing services to Medicaid beneficiaries.

Strengthens and Protects the Medicare Program. Consistent with the President's commitment to protect Medicare, the Budget proposes to improve program efficiency, enhance program integrity, and bolster program solvency to ensure the sustainability of the Medicare program for current and future generations. To accomplish this, the Budget works to restructure and bring transparency and accountability to payments that do not directly relate to Medicare's health insurance role,

by financing them outside the Hospital Insurance trust fund and modifying their growth rate. The Budget ensures payments accurately align with the costs of care to address perverse payment incentives identified by non-partisan experts that drive overutilization or clinically inappropriate use of more expensive sites of care. This would improve the quality of care seniors receive and better protect them from excessive out-of-pocket costs. The Budget also supports the Administration's commitment to reduce provider burden by providing hospitals and physicians freedom to use electronic health records as they deem best by removing ineffective Federal penalties and requirements, eliminating reporting burden and low-value metrics in performance-based payment for physicians, improving incentives for physicians to participate in advanced payment models that reward high-value health-care delivery, and providing CMS with greater flexibility in beneficiary education and quality assurance. The Budget creates a new option for Medicare beneficiaries to save for out of pocket healthcare expenses by allowing tax deductible contributions to health savings accounts associated with high deductible health plans offered by employers or Medicare Advantage. The Budget would extend Medicare's solvency by roughly eight years.

**Serves Older Americans.** The Budget prioritizes funding for programs that address the needs of older Americans, many of whom require some level of assistance to continue living independently or semi-independently within their communities. This funding provides critical help and support to seniors and caregivers. These programs provide direct services such as respite care, transportation assistance, and personal care services. These services also include \$838 million for senior nutrition programs. This funding is estimated to provide 222 million meals to 2.4 million older Americans nationwide.

Improves Treatment for Serious Mental Illness. The Budget requests new investments to improve treatment for individuals suffering from serious mental illness. Approximately 35 percent of the more than 10 million adults in the United States that suffer from serious mental illness did not receive mental health services in the past year. The Budget requests new investments to ensure more adults with serious mental illness receive Assertive Community Treatment, an evidence-based practice that provides a comprehensive array of services to reduce costly hospitalizations. The Budget also increases funding to improve mental health services for seriously mental ill individuals who are involved with the criminal justice system. The Budget maintains funding for the Community Mental Health Services Block Grant, which requires States to support services for first episode psychosis, which is vitally important to ensuring that individuals with serious mental illness receive appropriate treatment in a timely manner.

Enhances Emergency Preparedness and Health Security. The Budget proposes to transfer the Strategic National Stockpile to the HHS' Assistant Secretary for Preparedness and Response from the Centers for Disease Control and Prevention (CDC). This move consolidates strategic decision-making around the development and procurement of medical countermeasures, and streamlines leadership to enable nimble responses to public health emergencies. The Budget also prioritizes funding for the Biomedical Advanced Research and Development Authority, BioShield, and pandemic influenza, to continue to build on investments to protect the civilian population in the event of public health emergencies related to infectious disease outbreaks, and other man-made crises. A disease threat anywhere is a disease threat everywhere, so the United States will continue to support capacity building in other countries so that they can stop outbreaks at their source before they reach the U.S. homeland. Through CDC, the Budget proposes new investments via the Global Health Security Agenda to strengthen countries' abilities to respond to infectious disease outbreaks whether naturally occurring, accidental, or deliberate.

Accelerates Progress on Infectious Disease Elimination. Progress on fighting infectious diseases such as HIV/AIDS, viral hepatitis, sexually transmitted disease, and tuberculosis continues,

but much work remains—approximately 40,000 Americans are newly infected with HIV each year and there were more than two million cases of chlamydia, gonorrhea, and syphilis reported in the United States in 2016—the highest number ever recorded. The Budget requests \$40 million for a new demonstration initiative within CDC focused on jointly eliminating multiple infectious diseases using intensive prevention, screening, and treatment/referral as treatment efforts. This initiative would focus on at least five States/jurisdictions, particularly those that are seeing a rise in infectious diseases related to opioid abuse. The Budget also includes a focus on accelerating the elimination of perinatal HIV transmission in the United States.

Reauthorizes the Ryan White HIV/AIDS Program. The Ryan White HIV/AIDS Program provides a comprehensive system of primary medical care, treatment, and supportive services to over half a million people living with HIV, which is more than half of the people in the United States who have been diagnosed with HIV. The Budget supports reauthorizing the Ryan White program to ensure Federal funds are allocated to address the changing landscape of HIV across the United States. Reauthorization of the Ryan White Program should include data-driven programmatic changes as well as simplifying and standardizing certain requirements and definitions. These changes would ensure Federal funds may be allocated to populations experiencing high or increasing levels of HIV infections/diagnoses while continuing to support Americans already living with HIV across the Nation.

Addresses Overlapping and Burdensome Food Regulation. FDA will continue to work with the U.S. Department of Agriculture to streamline regulatory and inspection activities to ease burden on the industry by reducing the number of businesses that are inspected by both agencies. FDA will also support development of a State-based safety infrastructure by evaluating whether States will have an increased role in conducting inspections on larger farms on behalf of FDA and continuing outreach and education to small farms as they prepare for their upcoming compliance dates.

Reforms Federal Investments in the Healthcare Workforce. The Budget proposes to improve the effectiveness of Federal investments in the healthcare workforce to better address provider shortages. To better target Federal spending on graduate medical education (GME) and increase transparency and accountability, the Budget consolidates GME spending in Medicare, Medicaid, and the Children's Hospital GME Payment Program into a new mandatory GME capped grant program. Funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages. The Budget also proposes to eliminate \$451 million in other health professions and training programs, which lack evidence that they significantly improve the Nation's health workforce. The Budget continues to fund high value health workforce activities, such as the National Health Service Corps, that provide scholarships and loan repayment in exchange for service in areas of the United States where there is a shortage of health professionals.

Modernizes How the Government Employs Public Health Professionals. The U.S. Public Health Service Commissioned Corps (Corps) consists of over 6,500 uniformed public health professionals who work alongside their equivalent civilian counterparts performing the same day jobs but often receiving higher total compensation. The Corps receives military-like benefits, but has not been incorporated into the Armed Forces since 1952 and generally does not meet the Department of Defense's criteria for the military compensation system. Further, the Corps' mission assignments and functions have not evolved in step with the public health needs of the Nation. It is time for that to change. HHS is committed to providing the best public health services and emergency response at the lowest cost, and is undertaking a comprehensive look at how the Corps is structured. The specific recommendations and plans resulting from this analysis will be released in the months ahead and could range from phasing out unnecessary Corps functions to reinventing the Corps into a smaller, more targeted cadre focused on providing the most vital public health services and emergency response.

The goal of this proposal is to modernize how the Government employs public health professionals and how HHS responds to public health emergencies, saving Federal funds, and reducing duplication while safeguarding the well-being of the Nation.

Prioritizes Direct Health Services for American Indians and Alaska Natives. The Budget increases access to direct health services for American Indians and Alaska Natives by funding the staffing and operations of newly constructed facilities, extending services to three newly recognized Tribes, and increasing resources available for accreditation emergencies to address ongoing health-care delivery challenges in the Great Plains area.

**Prohibits Certain Abortion Providers from Receiving Federal Funds.** The Budget includes provisions prohibiting certain abortion providers from receiving Federal funds from HHS, including those that receive funding under the Title X Family Planning program and Medicaid, among other HHS programs.

Supports Children and Families in Achieving Their Potential. The Budget continues to invest in programs that help American families and children thrive. The Budget supports States in providing key services to children and youth by increasing State flexibilities and reducing administrative burdens in foster care. These child welfare reforms focus on preventing the need for foster care unless absolutely necessary to ensure families can remain intact. The Budget also helps working families afford and access child care by maintaining Federal funding for key HHS child care programs and using these investments to leverage additional State support for child care. In addition, the Budget promotes evidence-building and innovation to strengthen America's safety net, proposes improvements to the Temporary Assistance for Needy Families program, and supports efforts to get noncustodial parents to work. Together, these proposals reflect the Administration's commitment to helping low-income families end dependency on Government benefits and promote the principle that gainful employment is the best pathway to financial self-sufficiency and family well-being.

Rightsizes the Proper Role of the Federal Government. The Budget continues the 2018 Budget proposals to eliminate low-performing or ineffective programs, such as the Low Income Home Energy Assistance Program (LIHEAP) and the Community Services Block Grant (CSBG). Many States and utility companies currently provide energy assistance services, reducing the need for a distinct Federal program to fulfill this role. Further, LIHEAP is unable to demonstrate strong performance outcomes, and the Government Accountability Office has raised concerns about fraud and abuse in the program in the past. CSBG also has difficulty in demonstrating effective outcomes. In addition, eligible entities that receive funding from CSBG receive funding from many other sources, including other Federal sources. CSBG accounts for just five percent, on average, of total funding that these eligible entities receive, and these funds are distributed by a formula that is not directly tied to performance and outcomes.